

SHEER SATIN MINERAL SUNSCREEN TINTED- titanium dioxide, zinc oxide cream
INTEGRATIVE AESTHETICS BOSTON, LLC

Active Ingredients:

Titanium Dioxide 10% Zinc Oxide 3%

Purpose:

Sunscreen

Uses:

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings:

For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of the reach of children. If swallowed, get medical help or contact a poison control center right away.

Warnings:

Keep out of reach of children

Directions:

• Apply liberally 15 minutes before sun exposure. • Reapply: • After 80 minutes of swimming or sweating • Immediately after towel drying • At least every 2 hours • Children under 6 months: Ask a doctor • **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • Limit time in the sun, especially from 10 am-2 pm • Wear long-sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients:

Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Cetareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride,

Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water

Other Information:

Protect this product from excessive heat and direct sun. May stain some fabrics.

DRUG FACTS (cont)

INACTIVE INGREDIENTS: Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Cetareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics.



SHEER SATIN MINERAL SUNSCREEN

NON-COMEDOGENIC
CRUELTY-FREE
REEF FRIENDLY

TINTED

SPF 50 BROAD SPECTRUM
WATER RESISTANT
(40 MINUTES)

NET WT. 1.8 OZ / 53 G

DRUG FACTS

ACTIVE INGREDIENTS: Titanium Dioxide 10% Zinc Oxide 3%	PURPOSE: Sunscreen Sunscreen
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USES: Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early aging caused by the sun.

WARNINGS: For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

DIRECTIONS:

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - Reapply at least every 2 hours
- Children under 6 months: Ask a doctor
- **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 am- 2 pm
 - Wear long sleeve shirts and hats and sunglasses

Distributed by
ClearDermaceuticals, Inc
Watertown, MA 02472
www.cleardermaceuticals.com



SHEER SATIN MINERAL SUNSCREEN TINTED

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85306-258
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	100 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CI 77491 (UNII: 1K09F3G675)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CI 77492 (UNII: EX438O2MRT)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETEARETH-20 (UNII: YRC528SWJY)	
CI 77499 (UNII: XM0M87F357)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
MICA (UNII: V8A1AW0880)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISODODECANE (UNII: A8289P68Y2)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85306-258-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/07/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/07/2024	

Labeler - INTEGRATIVE AESTHETICS BOSTON, LLC (053676863)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85306-258)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85306-258)

Revised: 3/2025

INTEGRATIVE AESTHETICS BOSTON, LLC